

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Tarro and Brozzo

Serial No.

09/125,122

Examiner

Bunner, B.

Filed

January 4, 1999

Group Art Unit:

1647

FOR

PHARMACEUTICAL COMPOSITIONS

COMPRISING NATURAL HUMAN ALPHA-INTERFERON

## **AMENDMENT**

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on May 16, 2001.

Registration No.

Date of Signature

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

SIR:

In response to the Official Action dated December 4, 2001, please consider the following amendments and remarks. Applicants enclose herewith (1) A Petition to Extend Time for a period of three months, up to and including June 4, 2001, together with the required fee for a small entity; (2) a Declaration Under Rule 132 by Dr. Renzo Brozzo, one of the Applicants of the above-identified patent application; and (3) a Notice of Appeal, together with the fee required for a small entity.

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NY02:322182.1

#### **AMENDMENTS**

### IN THE SPECIFICATION:

Please substitute pages 1-12 of the originally filed specification with the pages 1-11 of the substitute specification supplied herewith.

# IN THE CLAIMS:

Please delete claims 8, 10, 12, 14, 16 and 18 without prejudice.

Please amend the claims as follows:

administering, to the subject, by the peroral route, an oral liquid formulation of natural human  $\alpha$ interferon at a daily docage of between 100 and 500 IU.

11. (amended) The method of claim 7 wherein the human α-interferon is obtained from lymphocyte cells.

Please add the following new claim:

20. (new) An article of manufacture comprising packaging material and a pharmaceutical agent in liquid formulation within said packaging material, wherein the pharmaceutical agent is therapeutically effective for treating viral hepatitis, and wherein the packaging material comprises a label which indicates that the pharmaceutical agent can be used for treating viral hepatitis and has to be administered through the peroral route at a daily dosage between 100IU and 500 IU, and wherein said pharmaceutical agent is natural human  $\alpha$ -interferon.

